International Journal of Scientific & Engineering Research, Volume 6, Issue 5, May-2015
ISSN 2229-5518

T Wave Based Control Algorithm for External Counterpulsation: A New Approach

Saranya.S and K.Mohanavelu

Abstract— External Counterpulsation (ECP) is a non-invasive therapeutic procedure for patients with Coronary Artery Disease (CAD), which is performed in synchronization with the patients' Electrocardiogram (ECG). This paper discusses a new algorithm developed to control the inflation and deflation of pressure bladders in ECP and also analyzes two other existing control algorithms. The two existing algorithms use the average of R-R Interval as the reference to control ECP functioning; while the newly developed algorithm is based on the detection of T wave end in ECG, which signifies the mechanical action of actual aortic valve closure in the cardiac function. It is emphasized and suggested that control algorithm based on aortic valve closure is more reliable and safe to control ECP functioning, as deflation has to occur well ahead of the opening of aortic valve; so that a lower vascular resistance is created during systole which decreases cardiac workload. The efficiency and reliability of all these three algorithms are also discussed.

Index Terms— CAD, ECG, ECP, T wave, Algorithm

I INTRODUCTION

CAD is the most common manifestation of cardiovascular disease and it is the leading cause of death worldwide. The World Health Organization (WHO) predicts it will remain as such for the next 20 years. By 2020, it is estimated that this disease will be responsible for a total of 11.1 million deaths globally[1]. In addition to its mortality burden, CAD is a leading cause of morbidity and loss of quality of life. The treatment options available for Coronary Artery Disease vary from medication to surgery based on the severity of CAD. For people who do not obtain adequate relief by taking medications and who do not qualify for an invasive procedure, a harmless, non-invasive, outpatient therapy, namely External Counterpulsation (ECP) has emerged as a safe and effective alternative to all invasive surgical procedures.ECP makes use of the fact that the coronary artery supplies blood to the heart muscles during diastole, when the Aortic Valve (AV) remains closed (S2) as shown in Fig. 1. and hence ECP aims increasing the coronary perfusion pressure during this filling phase of heart, thus providing blood supply to these blocked arteries by external means. The technique involves sequential inflation and deflation of compression bladders/cuffs wrapped around the patients' lower extremities[2],[3]. It usually involves the application of three air bladders at calf, lower thigh and upper thigh regions of both right and left leg, whose inflation/deflation are controlled by Solenoid Valves (SV) SV1, SV2 and SV3 respectively. The schematic diagram describing the technique is shown in Fig. 2. The bladders are inflated from calf to thigh to buttock; proximally during diastole, with rapid deflation of all bladders just before the beginning of systole. The mechanism and hemodynamic effects are similar to Intra Aortic Balloon Pumping (IABP) to augment

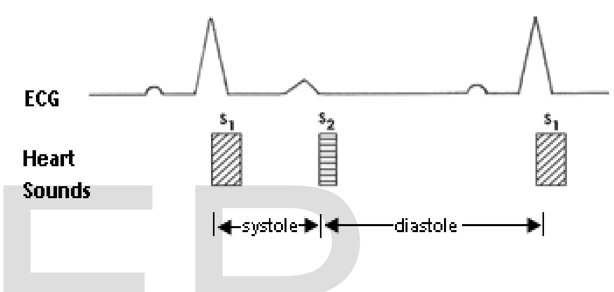
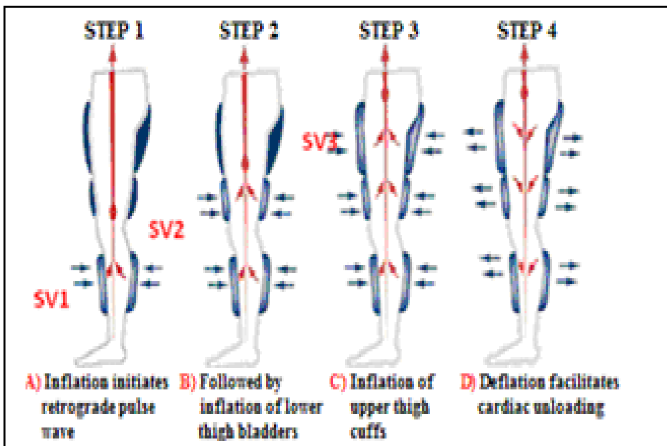


Fig 1. A typical ECG wave indicating systole and diastole phases of a cardiac cycle and the correlation with heart sounds.

diastolic pressure [4],[5],[6]. Unlike IABP, ECP also enhances venous return, further promoting an increase in cardiac output with a decrease in cardiac workload. These hemo dyna mic effects lead to increased blood flow in multiple vascular beds, including the coronary arterial circulation thatdevelops new pathways around blocked arteries called "collaterals". [7],[8],[9],[10].



(*Courtesy: Asian Cardiovasc Thorac Ann 2003 11:92-94)*

Fig.2. Enhanced external counterpulsation Technique

- *Saranya.S (Teaching Fellow) is with College of Engineering,Guindy, Anna University Chennai, India, E-mail: saranya.annauniversity@gmail.com*
- *K.Mohanavelu is a Scientist with Bioengineering and Electromedical Laboratory (DEBEL), Defence R&D Organization (DRDO), Bangalore-560 093, E-mail: mohanvelk@yahoo.com*

ISSN 2229-5518

The flow of pressurized air through the bladders is controlled by means of the opening and closing of SV, which is controlled based on diastole and systole using a software algorithm.

The existing algorithm used in real time applications calculates the inflation/deflation timings based on R-R Interval of the ECG signal. Two such algorithms are analyzed in this work and will be referred to as Algorithm 1 (patented by Pickett et al. (2009)) [11] and Algorithm 2 (patented by Hui (2008)) [12] respectively hereafter.

In this work, both the algorithms have been implemented and the timing of opening and closing of SV for inflation and deflation during each cardiac cycle are analyzed. The effectiveness and limitations of using beat to beat (R-R) interval of ECG as a reference is also discussed.

The final goal of this work is to suggest a new approach to determine the inflation/deflation timings (SV trigger time) based on T wave end which corresponds to the mechanical action of AV closure. This approach makes the control algorithm to be more robust and appropriate for ECP therapy since the reference considered is the exact timing of diastolic occurrence which makes sure that the deflation will essentially happen just before the systole occurrence. Hereafter the newly developed algorithm is referred as Algorithm III in this work.

II. ECP CONTROL ALGORITHMS

The general structure of ECP control algorithm is shown in Fig.3. Prior to defining the trigger time, Algorithms I and II involve a common step namely, finding the R-peaks in the ECG waveform using well established techniques. The R-peak detection is followed by estimating the R-R Interval and Heart Rate (HR). Both the algorithms specify an upper and lower limit for HR, the range within which ECP procedure is performed and the algorithm proceeds further to calculate inflation/deflation timings based on average of R-R Interval.

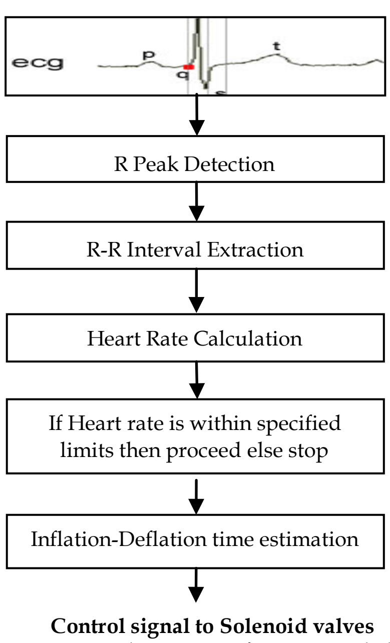


Fig. 3. General Structure of ECP control algorithm

A. Algorithm I: Suprapatellar External Counterpulsation Apparatus by Pickett et al.

This algorithm calculates the average of 8 consecutive R-R intervals and the upper and lower limit to start initiation of control signals is fixed as 90 bpm (0.67s – R-R Interval) and 45 bpm (1.33s) respectively. From the next consecutive R peak, the control signal to the first SV (bladders attached to the calf muscles) for inflation is initiated after 25% of average R-R interval. A delay of 40ms is introduced before the opening of the second SV and another 40ms delay for the opening of third SV. The deflation of all the three cuffs occurs simultaneously due to the closure of the three SVs which is fixed 370ms after the third SV opening. This is to ensure that there is sufficient time for the application of pressure to the lower limbs and for the pressure to reach the aortic root, before deflation starts. The limitation of this algorithm is that it works well for lesser HR of the order of 30-60 bpm, but the R-R Interval shortens gradually for increasing HR and hence the constant delay of 370ms results in the deflation control signal to be fired after the P-wave or beginning of QRS complex, thus making it very crucial for the entire deflation to complete before the occurrence of next R-peak (beginning of next systole).

B. Algorithm II: High Efficiency External Counterpulsation Apparatus by Hui et al

This method also involves the determination of R-R Interval and HR from the QRS Complexes identified. The upper and lower limits of HR are fixed as 120 bpm and 30 bpm respectively. The time of initiation of SV1 is determined in correlation with Bazett's formula (approximates the Q-T interval as 0.4 times the square root of R-R interval) and is given by equation 1,

$$T_1 = (12.65*\sqrt{T_R} + C1 -300)\ ms \quad (1)$$

Where, T_1 is the time interval from R-wave to the opening of SV1 in ms; T_R is the average R-R Interval in ms and C1 is a constant fixed at 210 ms. The timing for the SV1 to open corresponds to a region approximately the T wave peak, closely followed by the second and third SV openings with an intermittent delay of 50 ms. Though T wave end actually corresponds to the closure of AV, the reason for the SV1 to open well before T wave end is to accommodate the delay in the arrival of retrograde pressure caused by the pneumatic system used for the inflation of pressure bladders. Even though this delay will vary depending on the peripheral resistance of lower extremities for each person, practically each valve opens for 100ms during inflation of each bladder to reach maximum inflation pressure and 120 ms during deflation, as the bladder pressure should drop to zero upon deflation and no residual pressure should exist in the bladder at the beginning of the next systolic phase, giving the peripheral vascular bed enough time to refill during cardiac systole.

This algorithm calculates T_1 based on R-R Interval and the minimum fixed permissible value of T1 is 150 ms to make sure the leading edge of the retrograde pressure wave reaches the aortic root during the diastole. Once T_1 is determined the deflation time for simultaneous deflation of all the valves are calculated using the following equation 2,

$$T_2 = (T_R\text{-}C2)\ \text{ms} \qquad (2)$$

Where, T_2 is the time interval from preceding R wave to the opening of the deflation valves in ms; C2 is a constant initially fixed at 160ms and can be varied manually based on HR.This method depends on the delay T1 based on R-R interval and few other factors like the mechanical properties of the apparatus and physiological properties of the subject which also has influence on the time duration at which the pressure is received at the aortic root. Moreover the time interval between deflation signal and the next systolic R peak is fixed to 160ms irrespective of the occurrence of the third inflation control signal.

C. Algorithm III: External Counterpulsation Control Algorithm based on ECG T wave end

The Algorithms I and II, discussed above are purely based on R-R interval for the determination of inflation/deflation timings, irrespective of the diastolic interval that starts exactly at the T wave end and mechanically correlates with the closure of AV. As external Counterpulsation involves the inflation of bladders during cardiac diastole and deflation of bladders during systole, it would be more relevant if the inflation/deflation process is precisely timed in correlation with exact occurrence of diastole-systole rather than taking the average of R-R interval which only gives the combined duration of a systole-diastole cycle without any demarcations between them.

A new algorithm has been developed that aims at determining the inflation-deflation timing, considering the T wave end as an ideal point of reference. Hence, the T wave end is identified along with both present and next R peak in ECG. The R_p T_{end} and T_{end} R_n interval (where R_p and R_n indicates the present and next R peak respectively) in each cardiac cycle is identified from which inflation and deflation timings are calculated respectively. This new algorithm is depicted in the form of a flowchart as shown in Fig.4. The R peaks and T wave ends [12]. are detected using suitable time domain methods followed by the determination of R_p T_{end} and T_{end} R_n interval which denotes the systolic and diastolic period in an ECG cycle respectively.

Definitions of variables and their calculations are follows:

- V1 (in ms) = SV1 activation, is 1/3rd of R_p T_{end} interval subtracted from T wave end.
- V2 (in ms) = SV2 activation, 50ms after V1.
- V3 (in ms) = SV3 activation, 50ms after V2.
- D (in ms) = Simultaneous deflation activation of all three bladders, calculated by adding half of T_{end} R_n interval with T wave end.

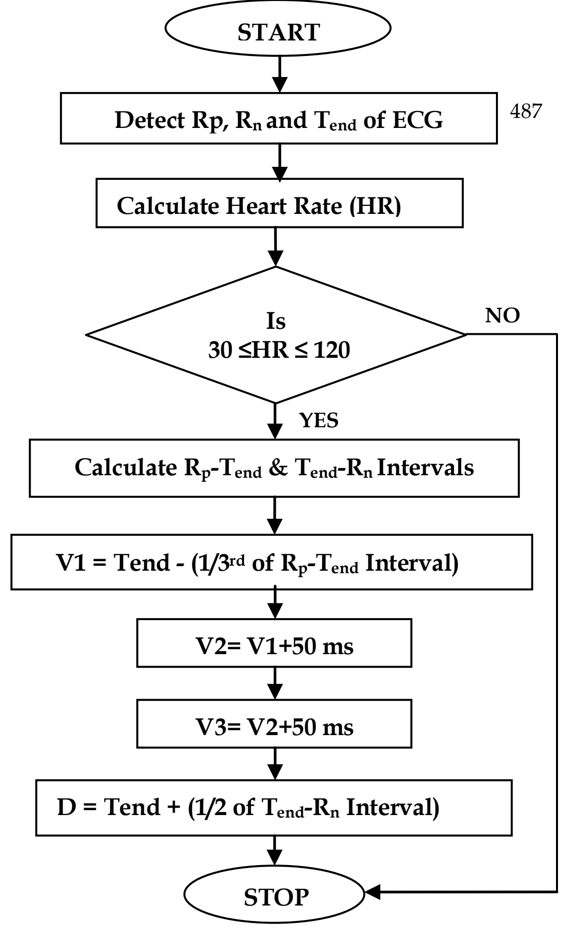


Fig.4. Flowchart describing the proposed algorithm

This method makes sure that the inflation and deflation of valves are correlated with the occurrence of T wave end denoting the beginning of cardiac diastole.

III. COMPARISON OF ALGORITHMS

All the above algorithms were implemented and results were obtained by processing ECGs with HR 30-120 bpm.

A. Graphical Analysis and Comparison of Algorithms

The results of employing all the three control algorithms on ECG for lowest HR (30 bpm) and highest HR (120bpm) considered, is shown in Fig. 5 (a) & 5 (b). In Fig 5 (a), it is shown that for the algorithms I and II, inflation begins after T wave end, whereas in Algorithm III all three inflation signals V1, V2 and V3 are fired at the T wave with V3 always lying close to the T wave end irrespective of the HR considered. This is because, V1, V2 and V3 denotes only the initiation of control signals to the SVs and each valve in turn takes some time to fully open and still more time for the air pressure to arrive at the pressure bladder to reach maximum inflation pressure. Algorithm III ensures that the full inflation pressure reaches the aortic root as soon as the AV closes thus making the utmost and effective use of the diastolic interval, for acquiring the complete benefits of ECP treatment. It can also be verified that algorithm III initiates V1 not less than 150 ms delay from R_p as comparable to algorithm II, even though first inflation starts early when compared to algorithms I & II.

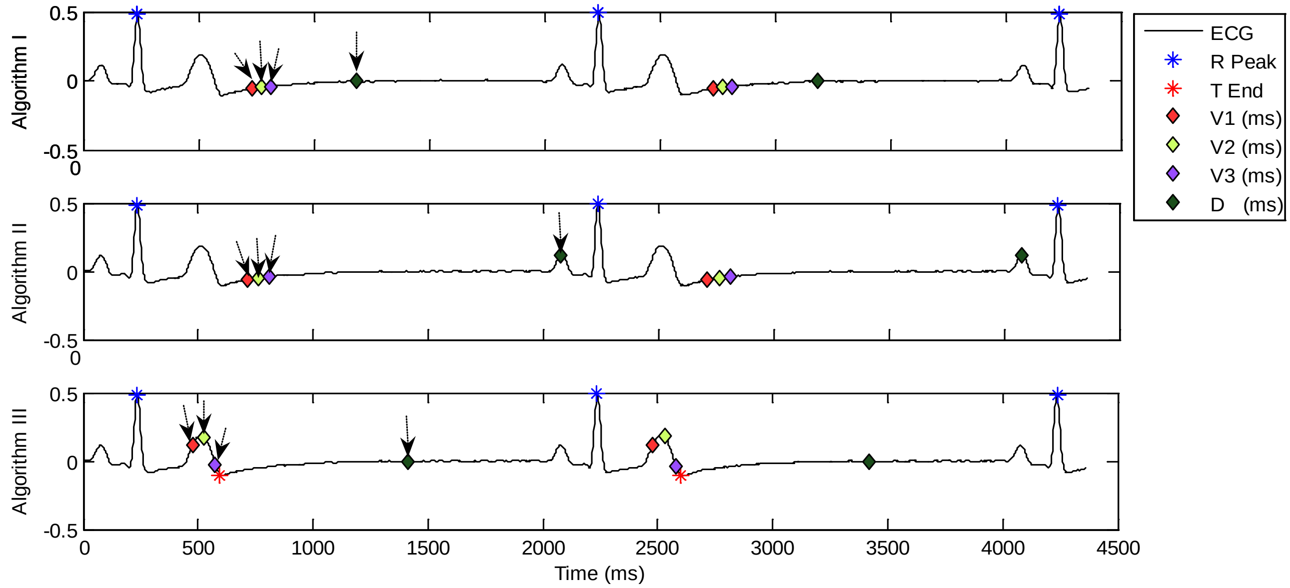


Fig.5 (a). Comparison of the three algorithms for ECG with a HR of 30 bpm

The inflation timings for HR 120 bpm, starts before the T wave end for all the three algorithms as shown in Fig. 5(b). If inflation was to actually start at the closure of AV then these time delays would result in pressure reaching at aorta long after the diastole, giving no time for deflation. For all the three algorithms, V1 maintains 150ms of fixed minimum delay as described in algorithm II, even for the highest HR of 120 bpm.

In case of V2 and V3, Algorithm I fixes a constant intermittent delay of 40ms, whereas algorithm II and III fixes 50ms delay between the valve openings. It should be noted that this delay purely depends on the valve dynamics and always solenoid valves with a very good response time are preferred.

On considering the deflation timings, algorithm I fixes the control signal D to be fired after constant delay of 370ms from V3, irrespective of HR. This criteria works well for lower HR less than 90 bpm (highest limit specified by the algorithm) as shown in Fig. 5(a). Algorithm II defines the deflation time to be set 160ms before R_n irrespective of the HR and the occurrence of V3. For lower HR [Fig.5(a)] there is sufficient amount of time left for deflation after V3, moreover as a result of sudden deflation just before the systole, the low resistance offered for systolic circulation decreases the workload of heart to a greater extent. Inspite of these advantages, it is always advisable to start deflation as early as possible so that the bladders are emptied in time and ready for the next inflation-deflation cycle and also if the deflation fails to occur due to unfavorable situations, there should be enough time to break the operation to avoid mishap.

Algorithm I certainly do not work well for higher HR above 100 bpm. It can be well noted from Fig.5 (b) that for 120 bpm, The deflation time for Algorithm 1 occur after R_n, which means that the bladders remain inflated during systole preventing the flow of blood to the limbs, thus invoking the risk of collapsing the entire circulation cycle, which may even prove fatal. In the case Algorithm II for higher HR [(fig.5(b)]

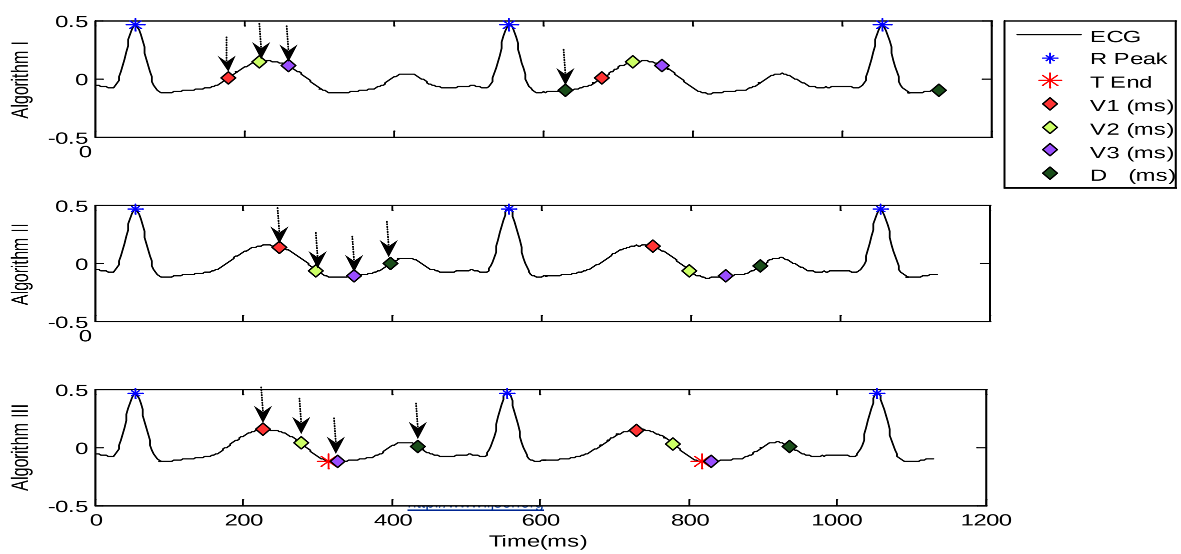


Fig.5 (b) Comparison of the three algorithms for ECG with a heart rate of 120 bpm

SV3 does not remain open for 100ms as scheduled, as the valves open for deflation prior to that. This may affect the entire amount of pressure designated to reach the aortic root. Hence it is always important to strike a balance between the inflation- deflation timings based on HR so that the maximum possible benefits due to ECP are obtained.

Algorithm III overcomes the above mentioned limitations by fixing the time of deflation to occur considering half of the TR interval as the ideal location for deflation. From Fig.5 (a) it can be verified that the deflation in algorithm III occurs well before that of algorithm II and Fig.5 (b) shows that there is sufficient time gap between V3 and D, compared to Algorithm II and the interval between D and R_n is approximately 120ms, which is the minimum time set by algorithm II for the deflation valves to remain open. Thus the proposed algorithm meets both these criteria enforced in Algorithm II.

B. Statistical Analysis of Algorithm II and Algorithm III

The algorithms are analysed for wide range of HR (30-120 bpm) using thirty records from MIT-BIH ECG database and also from our laboratory with twenty subjects ECG (Lead II) acquired with fixed sampling rate of 500 samples/sec. For each HR range, ten ECG data were used and all the three algorithms were employed to one particular cardiac cycle of all ten ECG data. The delay of V1, V2, V3 and D are computed from R_p for all the algorithms and their mean values for all five subjects in each HR range are termed as T1, T2, and T3 & Td respectively as shown in Table 1.

The statistical analysis of data obtained by the implementation of Algorithm II and the newly developed Algorithm III were performed by computing Bland-Altman plots for T1, T2, T3 and Td for various HR as shown in Figs. 6, 7, 8 & 9 respectively. The values reside well within ±2 standard deviation (S.D) which signifies good correlation between the already existing algorithm and the newly proposed algorithm.

IV) COMPARISON SUMMARY

Algorithm I works well for HR within 90 bpm but not reliable for higher HR. Though Algorithm II overcomes the above limitation by always fixing a constant delay which remains as the safe limit between the D and Rn, for higher HR the efficient time of inflation is not achieved because deflation occurs irrespective of the inflation duration. As a result the maximum benefit due to the treatment remains to be a question when higher HR are considered. Both Algorithms I and II consider only the average of RR Interval of ECG for the calculation of Inflation/Deflation timings, but consideration should be given to the fact that, ECP should be performed only during the diastolic phase of the cardiac cycle as it is the time when the aortic valve closes and the coronary artery receives blood to the heart muscle by perfusion pressure. In the proposed control algorithm, inflation/deflation cycle is timed based on the occurrence of T wave end and making use of the R_p T_{end} and T_{end} R_n interval of ECG for inflation and deflation respectively. The graphs and plots show that for a HR range of 30-120 bpm, the algorithm works consistently well, by making sure that the deflation time does not interfere with systole and also that there are no compromises made on the efficient time for inflation, proving to be more efficient and safe. The only limitation of the proposed algorithm is that it holds good only for ECG with prominent T wave. In case of non-specific ST-T changes in the ECG, detection of T wave end becomes a challenge and hence ECG in lead II configuration without any non-specific ST-T abnormalities are preferred to work with this algorithm.

V.CONCLUSION

This work is an effort to develop a new control algorithm for ECP therapy and also to compare and analyse the efficiency and reliability of the developed algorithm. The results obtained after implementing these algorithms shows a good insight on how safe each method is, with respect to change of HR. Only hundred ECG data has been collected and the

Table 1: Mean values T1, T2, T3 & Td for algorithms I, II and III computed for a wide HR

Heart Rate Range (bpm)	Algorithm I Mean Values (ms)				Algorithm II Mean Value (ms)				Algorithm III Mean Values (ms)			
	T1	T2	T3	Td	T1	T2	T3	Td	T1	T2	T3	Td
30-50	376	415	455	822	398	445	493	1344	254	349	301	1129
50-70	242	281	321	689	303	351	400	811	246	343	311	768
70-90	186	225	265	633	254	302	351	581	223	321	312	606
90-120	142	181	220	589	211	259	308	408	194	291	242	473

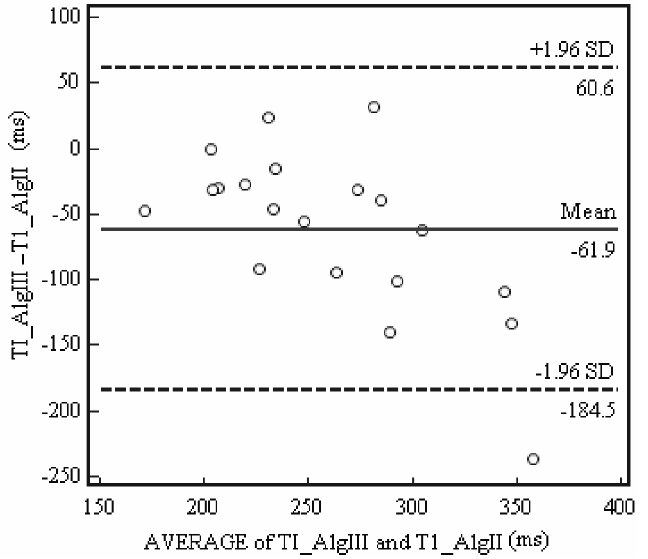


Fig.6. Bland Altman Plot of T1 for various HR range. The limits of agreement defined by ± 1.96 S.D above and below the bias are shown by dotted lines

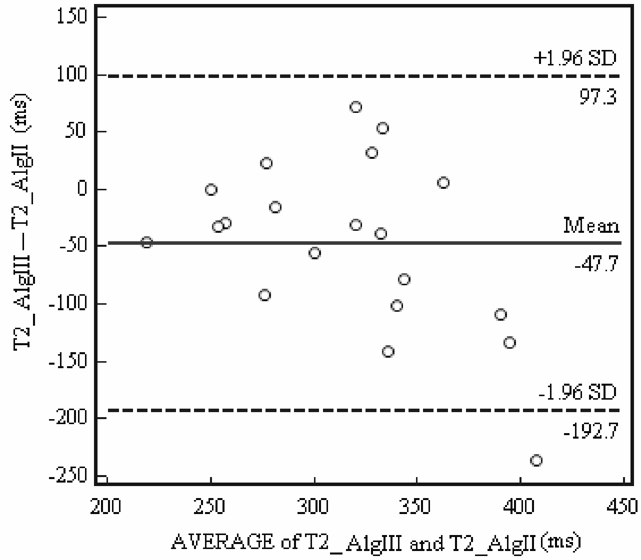


Fig.7. Bland Altman Plot of T2 for various HR range. The limits of agreement defined by ± 1.96 S.D above and below the bias are shown by dotted lines

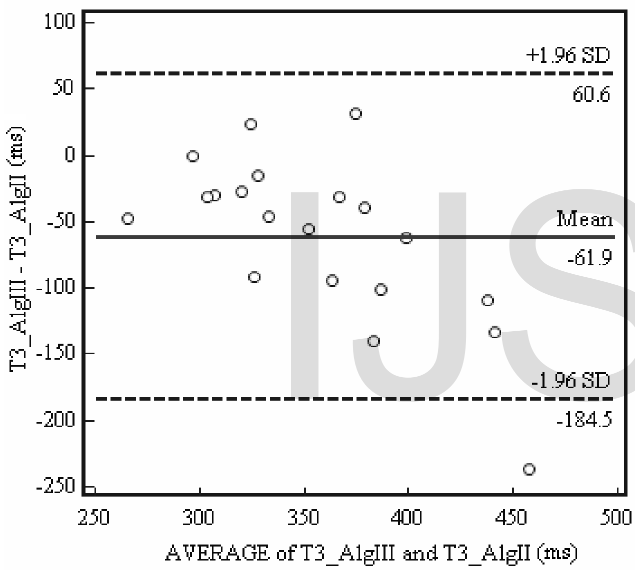


Fig.8. Bland Altman Plot of T3 for various HR range. The limits of agreement defined by ± 1.96 S.D above and below the bias are shown by dotted lines

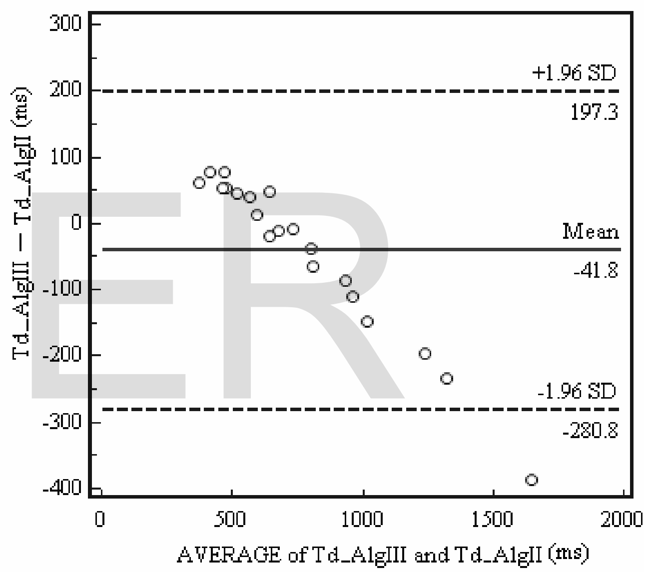


Fig.9. Bland Altman Plot of Td for various HR range. The limits of agreement defined by ± 1.96 S.D above and below the bias are shown by dotted lines

analysis has shown satisfactory results. As a part of the future work, the statistical analysis is extended by collecting a huge database for each HR range. However the Pneumatic system that works by using this control algorithm III has to be developed, to practically implement the algorithm along with additional facilities like manual control to change the inflation/deflation timings and verify the results for real time applications.

ACKNOWLEDGEMENT

The authors would like to extend their grateful thanks to Dr.V.C Padaki, Director, DEBEL, DRDO, Ministry of Defence, for giving permission and the facilities needed for successful completion of this work.

REFERENCES

[1] Mathers CD., Loncar D., "Projections of Global Mortality and Burden of Disease from 2002 to 2030", PLoS Med , Vol. 3(11):e442, pp. 2011-2030,2006.

[2] Masuda D, Nohara K, Kataoka K, et al." Enhanced external counterpulsation promotes angiogenesis factors in patients with chronic stable angina Circulation" 104II445,2001.

[3] Bonnetti PO, Barsness GW, Keelan PC, et al." Enhanced external counterpulsation improves endothelial function in patients with symptomat-

ISSN 2229-5518
ic coronary artery disease". J Am Coll Cardiol.,;pp.41:1761–8,2003.

[4] Arora RR, Lopes S, Saric M." Enhanced external counterpulsation im proves systolic function by echocardiography in patients with coronary artery disease". Heart Lung. pp. 34:122–5, 2005.

[5] Gorcsan J, III, Crawford L, Soran O, et al." Improvement in left ventricular performance by enhanced external counterpulsation in patients with heart failure" J Am Coll Cardiol 35230A(Abst) ,2000.

[6] Barsness GW., "Enhanced external counterpulsation in unrevascularizable patients", Curr Interv Cardiol, Vol. 3(1), pp. 37–43,2001.

[7] Arora RR, Lopes S, Saric M." Enhanced external counterpulsation im proves systolic function by echocardiography in patients with coronary artery disease". Heart Lung. pp. 34:122–5, 2005.

[8] Gorcsan J, III, Crawford L, Soran O, et al." Improvement in left ventricular performance by enhanced external counterpulsation in patients with heart failure" J Am Coll Cardiol 35230A(Abst) ,2000.

[9] Urano H, Ikeda H, Ueno T, Matsumoto T, Murohara T, Imaizumi T. "Enhanced external counterpulsation improves exercise tolerance, reduces exercise-induced myocardial ischemia and improves left ventricular diastolic filling in patients with coronary artery disease". J Am Coll Cardiol. pp.37:93–9,2001.

[10] Lawson WE, Hui JCK, Guo T, Burger L, Cohn PF." Prior revascularization increases effectiveness of enhanced external counterpulsation". Clin Cardiol.;pp.21:841–4.1998.

[11] Pickett D.A., Lusk J.R., "Suprapatellar External Counterpulsation Apparatus", US Patent 7597659 B2, 2009.

[12] Hui J.C.,"High Efficiency External Counterpulsation and Method for Controlling the Same" US Patent 7,314,478 B2,2008.

[13] Zhang Q., Manriquez A.I., Medigue C., Papelier Y., M. Sorine., "An algorithm for robust and efficient location of T-wave ends in electrocardiogram" IEEE Transactions on Biomedical Engineering, Vol. 53(12), pp. 2544-2552,2006.